IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. TEVA PARENTERAL MEDICINES, INC., APP PHARMACEUTICALS, LLC, PLIVA HRVATSKA D.O.O., TEVA PHARMACEUTICALS USA, INC., and BARR LABORATORIES, INC., Defendants.	)	Civil Action No. 1:10-cv-01376-TWP-DKL

STIPULATION REGARDING DEFENDANTS' PRODUCT LABELING

Plaintiff Eli Lilly and Company ("Lilly") and Defendants Teva Parenteral Medicines, Inc. ("Teva Parenteral"), Teva Pharmaceuticals USA, Inc. (collectively with Teva Parenteral, "Teva"), and APP Pharmaceuticals, LLC ("APP") (collectively "Defendants") jointly submit this stipulation regarding the January 29, 2015 trial in the above-captioned matter relating to the issue of whether the use of Defendants' Abbreviated New Drug Application ("ANDA") products in accordance with their accompanying product labeling infringes the asserted claims of U.S. Patent No. 7,772,209 ("the '209 patent").

WHEREAS:

1. The issues to be considered by the Court at the January 29, 2015 trial relate, in part, to the contents of the product labeling for the products identified in (a) Teva's ANDA Nos. 90-352 and 90-674 (including any amendments, supplements, or replacements thereto), and (b) APP's ANDA No. 90-384 (including any amendments, supplements, or replacements thereto) (collectively, "Defendants' ANDAs" and "Defendants' ANDA Products").

2. Subject to certain exceptions, a proposed product that is the subject of an ANDA must have product labeling that is "the same as the labeling approved for" a "listed drug" to which the ANDA refers. *See* 21 U.S.C. § 355(j)(2)(A)(v).

3. Lilly's ALIMTA® is the "listed drug" to which Defendants' ANDAs refer.

4. The product labeling for ALIMTA® was last updated in September 2013, which was after the close of fact discovery and the service of expert reports in this litigation.

5. The parties understand that, before Defendants' ANDA Products may receive any final FDA approvals, their product labeling may need to be modified to reflect recent changes to the ALIMTA® product labeling.

6. The product labeling for ALIMTA® and Defendants' ANDA Products consists of two parts: physician prescribing information and patient information. Defendants' physician prescribing information (APP: TX 2161; Teva: TX 2159, TX 2160) and patient information (APP: TX 2162; Teva: TX 2159, TX 2160) shall be referred to collectively herein as Defendants' Product Labeling.

THEREFORE, in an effort to simplify the presentation of the issues at trial, the parties stipulate and agree as follows:

7. The September 2013 ALIMTA® Physician Prescribing Information (TX 3018) and Patient Information (TX 3017) are admissible for purposes of the January 29, 2015 trial.

8. Other than (a) differences in the name of the manufacturer, name of the distributor, and/or name of the product, and (b) other differences not relevant to a determination of infringement or non-infringement, TX 3018 and TX 3017 shall be treated as reflecting the contents of Defendants' Product Labeling for purposes of determining infringement or non-infringement in this matter.

9. Thus, the parties may use TX 3018 in place of, and to the same extent as, Defendants' physician prescribing information (APP: TX 2161; Teva: TX 2159, TX 2160), and TX 3017 in place of, and to the same extent as, Defendants' patient information (APP: TX 2162; Teva: TX 2159, TX 2160). In the event that any party makes any showing or establishes any fact relating to infringement or non-infringement of the '209 patent by reference to TX 3018 and/or TX 3017, that demonstration shall have the same force and effect as if the party had made a corresponding showing or established a corresponding fact by reference to Defendants' Product Labeling.

10. The fact that TX 3018 and TX 3017 are different versions of the physician prescribing information and patient information, respectively, from the versions cited in the reports of Lilly's infringement expert (Dr. Bruce Chabner) and Defendants' non-infringement expert (Dr. Thomas Schulz) shall not be a basis to exclude opinion testimony about the contents of TX 3018 and TX 3017.

/s/ David M. Krinsky
Jan M. Carroll
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, IN 46204
(317) 236-1313
(317) 231-7433 (Fax)
jan.carroll@btlaw.com

Bruce R. Genderson
Adam L. Perlman
Ellen E. Oberwetter
Dov P. Grossman
David M. Krinsky
Andrew V. Trask
Christopher T. Berg
WILLIAMS & CONNOLLY LLP
725 Twelfth Street N.W.

/s/ Michael B. Cottler (with permission)
David O. Tittle
Kandi Kilkelly Hidde
Briana L. Clark
Ashley Paynter
BINGHAM GREENEBAUM DOLL LLP
10 West Market Street
Market Tower, Suite 2700
Indianapolis, IN 46204
(317) 635-8900
(317) 236-9907 (Fax)
dtittle@bgdlegal.com
khidde@bgdlegal.com
bclark@bgdlegal.com
apaynter@bgdlegal.com

Daryl L. Wiesen
Elaine H. Blais

Washington, DC 20005
(202) 434-5000
(202) 434-5029 (Fax)
bgenderson@wc.com
aperlman@wc.com
eoberwetter@wc.com
dgrossman@wc.com
dkrinsky@wc.com
atrask@wc.com
cberg@wc.com

Attorneys for Plaintiff Eli Lilly and Company

Emily L. Rapalino
GOODWIN PROCTER LLP
53 State Street
Boston, MA 02109
(617) 570-1000
dwiesen@goodwinprocter.com
eblais@goodwinprocter.com
erapalino@goodwinprocter.com

Michael B. Cottler
Brian J. Prew
Natasha E. Daughtrey
GOODWIN PROCTER LLP
620 Eighth Avenue
New York, NY 10018
(212) 813-8800
mcottler@goodwinprocter.com
bprew@goodwinprocter.com
ndaughtrey@goodwinprocter.com

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2015, I caused a copy of the foregoing to be served electronically via operation of the Court's CM/ECF system upon the following:

David O. Tittle
Kandi Kilkelly Hidde
Briana L. Clark
Ashley Paynter
BINGHAM GREENEBAUM DOLL LLP
dtittle@bgdlegal.com
khidde@bgdlegal.com
bclark@bgdlegal.com
apaynter@bgdlegal.com

Daryl L. Wiesen
Elaine H. Blais
Emily L. Rapalino
GOODWIN PROCTER LLP
dwiesen@goodwinprocter.com
eblais@goodwinprocter.com
erapalino@goodwinprocter.com

Michael B. Cottler
Brian J. Prew
Natasha E. Daughtrey
GOODWIN PROCTER LLP
mcottler@goodwinprocter.com
bprew@goodwinprocter.com
ndaughtrey@goodwinprocter.com

Attorneys for Defendants

/s/ David M. Krinsky